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FOR ACTION

RECOMMENDATION TO THE EXECUTIVE BOARD

Participation in the Children's Vaccine Initiative

The Executive Director recommends that the Executive Board approve an amount of $7.5 million from general resources, subject to availability of funds, and an amount of $7.5 million in supplementary funds, subject to the availability of specific-purpose contributions, for a three-year programme of cooperation with the World Health Organization and other partners for the period 1991-1993 to support the accelerated development of more vaccines to facilitate the achievement of the health goals adopted by the Executive Board and the World Summit for Children.

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INTRODUCTION

1. Ten years ago, nearly 5 million children died every year from immunizable diseases. During the past decade, this toll on children during their first year of life has been reduced dramatically through increased coverage of vaccines for measles; diphtheria, pertussis and tetanus (DPT); poliomyelitis; and tuberculosis. Neonatal tetanus deaths are also being reduced by immunizing women during or prior to pregnancy. In developing countries, at the end of 1989, coverage of children during their first year of life for three doses of DPT and polio vaccine had reached 75 and 78 per cent, respectively. Coverage of measles has more than tripled in five years to 71 per cent. Preliminary data for 1990 show a continued increase, and it is very likely that the goal of universal child immunization (UCI) by the end of 1990 (80 per cent for each antigen) will have been reached.

2. It has been estimated that attaining the 80 per cent mark will significantly reduce deaths from measles, pertussis, diphtheria and poliomyelitis to approximately 1.8 million per year. True universal protection has not yet been achieved for several reasons: the vaccines are not 100 per cent effective and are often given too late; infants or their mothers do not receive the full series and become drop-outs; and some vaccines lack adequate stability to withstand heat and, therefore, become impotent before use.

3. Because of success to date in improving immunization coverage, the World Health Assembly has set goals for eradicating poliomyelitis globally by the year 2000; eliminating neonatal tetanus by 1995; reducing measles cases and mortality by 90 and 95 per cent, respectively, by the year 2000; and increasing coverage of children under one year old to 90 per cent by the year 2000. These goals have been endorsed by the World Health Organization (WHO)/UNICEF Joint Committee on Health Policy and the UNICEF Executive Board at the 1989 session, as well as by the World Summit for Children.

I. THE NEED FOR NEW AND IMPROVED VACCINES

4. Experts feel that it will be difficult to achieve those goals without improving the vaccines currently used in the expanded programme on immunization (EPI), which protects against six vaccine-preventable diseases (see para. 1 above). Because the global immunization programme is now able to reach an estimated 100 million infants per year, an extraordinary opportunity exists to deliver existing or new vaccines to protect against other diseases that afflict children.

5. WHO estimates that an additional 5 million to 6 million annual deaths from viral and bacterial diseases such as bacterial diarrhoeas, hepatitis A, C and E, rotavirus, meningococcal meningitis, dengue and acute respiratory infections (ARI) could be prevented with new vaccines which either already have been or could be developed with existing technologies. Millions of lives could also be saved each year by an effective vaccine against malaria.

6. It is widely recognized that the development of ideal vaccines is an incremental process that will build upon the improvement of current vaccines. For example, the protection of the newborn against tetanus requires either a clean delivery and care of the umbilicus or tetanus toxoid vaccine, which is given to the mother before or during pregnancy. For lifetime protection, five doses are required at appropriate intervals, or two doses during pregnancy if a mother has not previously been immunized. The coverage rate for two doses for pregnant women in 1989 was only some 44 per cent (excluding China), and the drop-out rate is quite high. Therefore, the major objective for improving tetanus toxoid vaccine is to develop a timed-release preparation that would require only one injection for lifetime protection.

7. Poliomyelitis has nearly been eliminated in many industrialized countries and is expected to be eliminated in the Americas hemisphere by the end of 1990 through extensive use of the Sabin-derived oral polio vaccine. The efficacy of the oral vaccine currently used has been lower than expected in many developing countries, however. Changes in the formulation recommended by the WHO EPI Global Advisory Group are being implemented and will require continued investigation and monitoring. The attenuated live polio vaccine is also the most heat-sensitive of the EPI vaccines and requires a rigorous cold chain. A further problem is that, although it is among the safest vaccines ever used, it is capable of producing paralysis in very rare cases. Although this is rare (1 case in every 2 million to 4 million doses given), it becomes important as levels of the disease are greatly reduced. Priorities for polio vaccines will then be to improve the immunogenicity, heat stability and safety of the oral vaccine. Field studies are also needed to find the most effective vaccine schedule and to ascertain whether combining oral and injectable polio vaccines increases efficacy.

8. It is recommended that the current measles vaccine be given to infants at nine months of age, but in some areas of the world many children contract measles before that age. The WHO EPI Global Advisory Group has recommended a high-potency Edmondston-Zagreb strain of vaccine for use at six months of age in highly endemic countries, notably in Africa, where measles is a significant cause of death before nine months of age. Further work is needed to ensure adequate supplies for global use of this or equally or more immunogenic strains of measles vaccine. The ultimate aim is an oral vaccine that can be given shortly after birth.

II. EXISTING UNICEF SUPPORT TO IMMUNIZATION ACTIVITIES

9. UNICEF has supported the global immunization programme during the past 10 years by providing a significant portion of the vaccines used in developing countries, much of the cold-chain equipment needed to protect those vaccines and injection and sterilization equipment. UNICEF support has also included the provision of vehicles to distribute vaccines and facilitate programme management, training for health workers and resources for communications and social mobilization activities. UNICEF has spent nearly $500 million for immunization activities since 1980.

10. The UNICEF supply system has very effectively procured vaccines at low cost both for donation to programmes and on behalf of Governments and Rotary International. A total of 4,408.7 million doses have been procured since 1982 at a cost of $177.2 million. The demand for UNICEF-procured vaccines will continue to rise as coverage increases and disease eradication programmes accelerate. The Supply Division estimates that a total of 5,557 million doses will be procured over the next five years at a cost of approximately $362.6 million. Many countries have already requested that UNICEF provide hepatitis B vaccine and the triple antigen vaccine for measles/mumps/rubella (MMR). Continued support has also been requested to upgrade and replace the cold chain and to provide injection and sterilization equipment. Both will be required in order to sustain the immunization programme in most developing countries during the next several years.

III. THE CHILDREN'S VACCINE INITIATIVE

11. A proposal for UNICEF collaboration with WHO and other agencies to provide modest resources for vaccine development was presented to the Executive Board at its 1990 session (E/ICEF/1990/P/L.39). In decision 1990/11, the Board requested the Executive Director to convene a meeting of experts, in collaboration with WHO, to ascertain the potential for new and improved vaccines and to elaborate a mechanism for effectively achieving these goals and report to the Board with an appropriate proposal at the earliest opportunity.

12. In response to this request, a series of meetings were held and the concept of new and improved vaccines received attention and support from government leaders, scientists and the entire development community. At a meeting of international experts jointly sponsored by WHO and UNICEF, held at UNICEF House on 10 September 1990, an important consensus, known as the Declaration of New York, was reached (see the annex to the present document for the full text; the list of participants is available upon request). The Declaration concludes that scientific progress, matched with improved capacities of all countries to immunize their children, provides an unparalleled opportunity to save additional lives and prevent millions of disabilities annually through a global children's vaccine initiative. It states that universal immunization will be facilitated by accelerating the application of current science to make new and better vaccines that will benefit children in both developing and industrialized countries. The experts also emphasized that research on vaccines must be accompanied by concurrent investments that would facilitate large-scale use, as well as inexpensive production in both industrialized and developing countries, improvements in the capacity for storing, handling and administering the vaccines and strengthening national epidemiological and applied research capacity in developing countries. This group of experts urged the world community to support a children's vaccine initiative and requested WHO to establish an international task force for vaccine development, together with the United Nations Development Programme (UNDP), UNICEF, the World Bank and other interested international, national, public and private organizations, in order to coordinate their efforts and ensure adequate support for the Initiative.

13. The goal of the initiative is to accelerate and facilitate the development of new and improved vaccines that:

(a) Would require one or two rather than multiple doses;

(b) Could be given earlier in life;

(c) Could be combined in novel ways, thus reducing the number of required injections or visits;

(d) Would be more heat stable and could remain potent during transport and storage, especially in tropical climates;

(e) Could in future possibly be effective against many diseases not currently feasible for inclusion in immunization programmes, such as acquired immunodeficiency syndrome (AIDS), ARI, diarrhoeal diseases and important parasites;

(f) Would be affordable for use in developing countries.

14. The launching of the children's vaccine initiative received enthusiastic attention and political support at the World Summit for Children as a priority activity for the 1990s. It is now being organized with a broad base of support from WHO, UNDP, the World Bank and several national and international organizations, including the private sector.

15. The Initiative will attempt to accelerate the development of new vaccines that will protect against and reduce the loss of young lives from diarrhoeal diseases and ARI. The use of such vaccines, together with appropriate case management, will clearly enhance the ability to reach the global goals of reducing diarrhoeal disease deaths by 50 per cent and reducing deaths due to ARI by one third by the year 2000.

A. Obstacles to the development of new and improved vaccines

16. In both the public and private sectors, there are at present a large number of potential new "candidate" vaccines, several of which are based on recombinant technology using carrier viruses that have the potential of incorporating a wide range of antigens. Considerable progress has also been made in polymer technologies, which are likely to lead to the development of single-dose, sustained-release oral vaccines that could replace multi-dose injectable vaccines. A single-dose tetanus vaccine is currently being developed using this technology.

17. There are several major obstacles to accelerating the development of candidate vaccines, which must meet the rigorous delivery demands of the developing world. First among these obstacles is the reluctance of private sector manufacturers to invest their resources in the scale-up, field testing and licensing of vaccines for which there is no major market in the industrialized world that would allow them to recover their development

costs. As a result, vaccine development has been driven principally by the needs of markets in the industrialized world, as opposed to those of the developing world.

B. International Consultative Group for Vaccine Development

18. In order to enhance collaboration and resource mobilization, an International Consultative Group for Vaccine Development is being convened by WHO. The Group will be composed of representatives of donor agencies, interested national vaccine research programmes and liaison representatives to the private sector. A chairman and an executive committee will oversee the activities of an inter-agency secretariat that will conduct daily operations.

19. With the assistance of the appropriate expert technical advisory groups, the Group will undertake to accelerate vaccine development in a variety of ways, including:

(a) Identifying short- and medium-term research and development priorities and disseminating and advocating them widely within the scientific community, in both the public and private sectors, through workshops, meetings and accelerated communication between interested parties;

(b) Identifying important basic research, vaccine development and operations research proposals and working with national vaccine research programmes, WHO (including the Programme for Vaccine Development) and donor agencies in identifying necessary financial resources, peer review and grants management;

(c) Facilitating the necessary partnership between national, international and private sector research, development and regulatory concerns on specific activities of potential importance;

(d) Identifying promising candidate vaccines and potentially important related technologies to the developing world and assembling product advisory groups and task forces to oversee and facilitate their expeditious development and testing, with the assistance of appropriate inter-institutional partnerships, including identifying technical, institutional and financial resources for filling gaps in the research, development, testing and regulatory processes;

(e) Identifying suitable sites for field trials and mobilizing the necessary technical and financial resources to establish sufficient epidemiological, monitoring and management expertise to assure their effectiveness and reliability.

C. UNICEF support for the children's vaccine initiative

20. In order actively to support the disease reduction goals that UNICEF has endorsed and to capitalize upon the proven strengths of UNICEF in vaccine procurement and programme support at the field level, as well as to increase the cost-effectiveness of UNICEF investment in child survival activities, it is proposed that UNICEF participate as a full partner in the children's vaccine initiative by providing financial support to key catalytic activities that can accelerate the achievement of the Initiative's goals.

21. UNICEF support will include:

(a) Staff support to the inter-agency secretariat of the International Consultative Group so as to facilitate close cooperation and coordination with UNICEF-supported procurement, programmes, operations research and EPI activities, and to support activities to coordinate information exchange, formulate priorities and promote and facilitate collaboration and resource mobilization among organizations, both public and private;

(b) Support for critical meetings and activities to facilitate acceleration of the vaccine development process;

(c) Support to selected clinical and field trials in developing countries to test new and improved vaccines and immunization schedules, and priority injection, sterilization and cold-chain equipment, as identified by the Group, with appropriate WHO oversight;

(d) Support for the development of candidate vaccines, field level diagnostic tests and other tools identified as high priorities by the Group, with appropriate partnerships for peer review and grants management;

(e) Support for operational research to improve the capacity to monitor and evaluate disease reduction and to improve the efficiency of delivery and demand for immunization services;

(f) Support for strengthening epidemiologic capacities required to strengthen existing EPI activities, facilitate field trials and enhance efforts to meet the immunization goals of the 1990s, including polio eradication, measles control and neonatal tetanus elimination;

(g) Collaboration with the WHO EPI to improve injection technology, sterilization equipment and cold-chain technology, to support operations research to improve the effectiveness and efficiency of vaccine delivery and administration at the field level and to strengthen national and global capacities for epidemiology and for monitoring evaluation of progress towards the goals of the Initiative.

IV. RECOMMENDATION

22. The Executive Director recommends that the Executive Board approve an amount of $7.5 million from general resources, subject to the availability of funds, and an amount of $7.5 million in supplementary funds, subject to the availability of specific-purpose contributions, for the children's vaccine initiative.

Breakdown of estimated annual expenditure

(In thousands of United States dollars)

	1991	1992	1993	Total
General resources	2 500	2 500	2 500	7 500
Supplementary funds	2 500	2 500	2 500	7 500
Total	5 000	5 000	5 000	15 000

Annex

DECLARATION OF NEW YORK: THE CHILDREN'S VACCINE INITIATIVE

10 September 1990

Children represent the most vulnerable segment of every society - and they are our present and the future. Good health, especially of children, promotes personal and national development. Scientific progress, matched with improved capacities of all countries to immunize their children, provides an unparalleled opportunity to save additional lives and prevent additional millions of disabilities annually through a global children's vaccine initiative.

Working together, national and international agencies, service organizations and private voluntary agencies around the world have demonstrated the feasibility of providing immunization to over 70 per cent of children in the developing world, saving approximately 2 million to 3 million children per year from those preventable diseases. Furthermore, countries around the world have demonstrated public interest in mobilizing to protect their children. With universal immunization using the current vaccines, 2 million to 3 million more deaths could be prevented annually. Development of new vaccines against diseases could save another 5 million to 6 million lives annually during this decade.

Universal immunization will be facilitated by accelerating the application of current science to make new and better vaccines, benefiting children in all countries. These include vaccines which:

(a) Require one or two rather than multiple doses;

(b) Can be given earlier in life;

(c) Can be combined in novel ways, reducing the number of injections or visits required;

(d) Are more heat stable, retaining potency during transport and storage, particularly at tropical temperatures;

(e) Are effective against a wide variety of diseases not currently targeted by immunization but which take a heavy toll of needless deaths, including AIDS, ARI, diarrhoeas and important parasites;

(f) Are affordable.

Work on vaccines themselves must be accompanied by investments that bring them rapidly into large scale and inexpensive production and effective use. Such investments are needed to simplify production and quality control methods; to support field trials; to speed licensing; to develop approaches -

including production in developing countries - which assure that vaccines are available for all, to simplify the logistics of storing, transporting and administering vaccine and to strengthen national epidemiological and applied research capacities, especially in developing countries, so that each vaccine is used to best advantage.

We, an international group of experts in the field of research and application of vaccines, acting in our individual capacities to review the great contribution that new and improved vaccines can make during the current decade to the health of all the world's children:

1. Urge national leaders, the heads of national and international agencies concerned with vaccine development and use, commercial enterprises and private and voluntary groups - harnessing the scientific and technical capacity of the world, North and South - to commit themselves to a children's vaccine initiative that aims to produce and deliver "ideal children's vaccines", which provide lasting protection against a wide range of diseases, need fewer contacts, have more heat stability, are simpler to administer and are affordable;

2. Request the World Health Organization, in fulfilment of its constitutional mandate as the directing and coordinating authority on international health work, to catalyse global efforts toward these ends by taking the lead in establishing an International Task Force for Vaccine Development, with the United Nations Development Programme, the United Nations Children's Fund, the World Bank and other interested international, national, public and private organizations, to coordinate their efforts through exchanging information, agreeing upon priorities, monitoring and evaluating research results, helping to organize and coordinate clinical trials of vaccines, promoting the development, production and incorporation of improved and new vaccines into national immunization programmes and facilitating resource mobilization.